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09/872,881	06/01/2001	Akira Suyama	14683	3628

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/872,881

Applicant(s)

Suyama

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 1, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/872,881
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2,4 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, and 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 2, and 8-16, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claims 1, 2 and 8-13 are also rejected over the recitation of the phrase, "binding the binding molecule". It is not clear which binding molecule is claimed to be bound. Is it the probe (A+B) or the label or the target or all of them or a complex of all of them? The metes and bounds of the claims are vague and indefinite.

Claims 13-16 are also rejected over the recitation of the phrase, "bounded" in claim 13. It is not clear what is claimed in this invention. It is suggested to change the phrase to "bound".

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73

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USPQ 482 (CCPA 1947). The term "SD" in claims 13-16 is used by the claims to mean "a sequence unit," while the accepted meaning is "standard deviation." It is also not clear if the units named as "SD, D0, D1 and ED" are made of some specific sequences or they are randomly selected with any sequences. The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2 and 13-16 are rejected under 35 U.S.C. 103(a) over Carr (European patent Application, Publication NO: 0 246 864) (May 19, 1987) in view of Cantor et al. (U.S. Patent 6,007,987) (December 28, 1999).

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Carr teaches a method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen (Abstract) comprising:

- a) preparing a probe A and a probe B (Abstract and Claim 1 and Example 1),
the probe A being a first probe which has a sequence F' complementary to a first partial sequence F of the target nucleic acid and a binding molecule bound to the sequence F' (Page 8, lines 41-42), and
the probe B being a second probe which has a sequence S' complementary to a second partial sequence S of the target nucleic acid (Page 6, lines 1-7);
- b) hybridizing the first probe A with the first partial sequence F of the target nucleic acid and hybridizing the second probe B with the second partial sequence S of the target nucleic acid (Page 6, lines 1-7 and lines 30-32 and Claim 2);
- c) ligating the first probe A and the second probe B both being hybridized with the target nucleic acid, thereby obtaining a probe (A+B) (Page 6, lines 30-33 and Claim 2 and Example 1);
- d) binding the binding molecule to a substance capable of being paired up therewith, or by denaturing the hybridized complex thereby recovering the probe (A+B) (Page 6, lines 34-36 and 47-55 and Claim 7); and
- e) recovering a single-stranded nucleic acid having the marker substance detected or identified, thereby detecting or quantifying the target nucleic acid in the specimen (Page 6, lines 13-23).

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Carr teaches the amplification of the single-stranded nucleic acid present in a liquid phase by PCR, thereby performing an encode reaction (Page 6, lines 30-35 and Claim 4).

Carr does not teach a probe with a double-stranded flag containing 4 units consisting of SD, D0, D1 and ED each having an arbitrary sequence bound to each other sequentially in the order mentioned and a marker substance.

Cantor et al teach a probe with a double-stranded flag containing 4 units consisting of SD, D0, D1 and ED each having an arbitrary sequence bound to each other sequentially in the order mentioned and a marker substance (Column 4, lines 9-17 and Column 7, lines 9-34 and column 9, lines 11-25).

Carr does not teach the multiplexing of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen with multiple probes A1-An and B1-Bn.

Cantor et al teach the multiplexing of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen with multiple probes A1-An and B1-Bn (Column 4, lines 9-17 and Column 7, lines 9-34 and column 9, line 11 to Column 10, line 52).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine a probe with a double-stranded flag containing 4 units consisting of SD, D0, D1 and ED and the multiplexing of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen with multiple probes A1-An and B1-Bn of Cantor et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr, since Cantor et al state, "These arrays may be

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bound to solid supports and are useful for determining the nucleotide sequence of unknown nucleic acids and for the detection, identification and purification of target nucleic acids in biological samples (Column 4, lines 13-16)". Moreover, Cantor et al. state, "A principal advantage of this probe is in its structure. Hybridization of the target nucleic acid is encouraged due to its favorable thermodynamic conditions established by the presence of the adjacent double-strandedness of the probe (Column 7, lines 29-33)". By employing scientific reasoning, an ordinary artisan would have substituted and combined a probe with a double-stranded flag containing 4 units consisting of SD, D0, D1 and ED and the multiplexing of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen with multiple probes A1-An and B1-Bn of Cantor et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in order to improve the detection and identification of multiple target nucleic acids. An ordinary practitioner would have been motivated to combine and substitute a probe with a double-stranded flag containing 4 units consisting of SD, D0, D1 and ED and the multiplexing of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen with multiple probes A1-An and B1-Bn of Cantor et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr, in order to achieve the express advantages noted by Cantor et al., of the structure of probes which provides hybridization of the target nucleic acid encouraged due to its favorable thermodynamic conditions established by the presence of the adjacent double-strandedness of the probe and also to achieve the express advantages of arrays of

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probes which are useful for determining the nucleotide sequence of unknown nucleic acids and for the detection, identification and purification of target nucleic acids in biological samples.

5. Claims 1-9 and 13-16 are rejected under 35 U.S.C. 103(a) over Carr (European patent Application, Publication NO: 0 246 864) (May 19, 1987) in view of Cantor et al. (U.S. Patent 6,007,987) (December 28, 1999) further in view of Wong (U.S. Patent 5,935,793) (August 10, 1999).

Carr in view of Cantor et al teach the method of claims 1-2 and 13-16 as described above.

Carr in view of Cantor et al do not teach the hybridization of the tag sequence Tg with a complementary sequence tag Tg' to recover the probes.

Wong teaches the hybridization of the tag sequence Tg with a complementary sequence tag Tg' (Example 2, Column 24, lines 24-30).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the hybridization of the tag sequence Tg with a complementary sequence tag Tg' of Wong into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al., since Wong states, "This results in an increased quantity of identifier tag with a relative reduction in sample-derived background, so that sensitivity for detecting the identifier tag on a probe-array can be substantially increased (Column 10, lines 19-22)". By employing scientific reasoning, an ordinary artisan would have substituted and combined the hybridization of the tag sequence Tg with a complementary sequence tag Tg' of Wong into the method of detecting or quantifying a

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target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al. in order to improve the detection and identification of multiple target nucleic acids. An ordinary practitioner would have been motivated to combine and substitute the hybridization of the tag sequence Tg with a complementary sequence tag Tg' of Wong into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al. in order to achieve the express advantages noted by Wong, of a method that results in an increased quantity of identifier tag with a relative reduction in sample-derived background, so that sensitivity for detecting the identifier tag on a probe-array can be substantially increased.

6. Claims 1-2 and 10-16 are rejected under 35 U.S.C. 103(a) over Carr (European patent Application, Publication NO: 0 246 864) (May 19, 1987) in view of Cantor et al. (U.S. Patent 6,007,987) (December 28, 1999) further in view of Cleuziat et al. (U.S. Patent 6,218,151 B1) (April 17, 2001).

Carr in view of Cantor et al teach the method of claims 1-2 and 13-16 as described above.

Carr in view of Cantor et al do not teach the sequencing by transcription of a single stranded nucleic acid by use of two primers.

Cleuziat et al. teach the sequencing by transcription of a single stranded nucleic acid by use of two primers. (Figure 13 and Column 29, line 39 to Column 30, line 6).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the sequencing by transcription of a single stranded nucleic acid by use of two primers. of Cleuziat et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al., since Cleuziat et al state, "The method is therefore composed of a single stage, without subsequent or intermediate addition of reagents, or the use of enzymatic activity, in particular nuclease activity (Column 30, lines 3-5)". By employing scientific reasoning, an ordinary artisan would have substituted and combined the sequencing by transcription of a single stranded nucleic acid by use of two primers. of Cleuziat et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al., in order to improve the detection and identification of nucleic acids. An ordinary practitioner would have been motivated to combine and substitute the sequencing by transcription of a single stranded nucleic acid by use of two primers. of Cleuziat et al. into the method of detecting or quantifying a target nucleic acid having a predetermined sequence in a specimen of Carr in view of Cantor et al., in order to achieve the express advantages noted by Cleuziat et al., of the method composed of a single stage, without subsequent or intermediate addition of reagents, or the use of enzymatic activity, in particular nuclease activity.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1655
September 24, 2001


JEFFREY FREDMAN
PRIMARY EXAMINER